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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,117	03/11/2004	John P. Mullally	MUJ-104-A	8807

7590 07/17/2009

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EXAMINER	
JAGOE, DONNA A	
ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
07/17/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/798,117	MULLALLY, JOHN P.	
	Examiner	Art Unit	
	Donna Jagoe	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2008 and 12 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-13 and 15-20* is/are pending in the application.

4a) Of the above claim(s) *10-13 and 15-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments filed March 12, 2009 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1 and 3-9 are pending in this application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 and 3-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lipworth et al. (U), Ridker et al. U.S. Patent No. 6,040,147 A and Faham et al. U.S. Patent No. 6,723,348 B2.

Lipworth et al. teach that there is an association between allergic inflammation in the upper airway and the lower airway and up to 40% of patients with asthma have allergic rhinitis and vise versa and since one will affect the other, neither condition should be treated in isolation (page 878, column 1, 1st paragraph).

Further, Lipworth et al. teach administration of leukotriene inhibitors such as montelukast and zafirlukast along with loratadine (page 878, column 2) and propose treatment options to include the use of the combined mediator blockade (antihistamine and leukotriene inhibitor) to facilitate the use of lower maintenance doses of topical corticosteroid. Recited corticosteroids include budesonide and mometasone (page 879, column 1). Lipworth teach effective doses of leukotriene inhibitor (montelukast 10 mg/day) and cetirizine (10 mg/day) as well as budesonide and mometasone 400µg daily and 200 µg daily (page 879, column 1).

It differs in that Lipworth et al. does not teach the reduction of C-reactive protein. Ridker et al. teach that C-reactive protein is a marker for underlying systemic inflammation (column 1, lines 60-61). It would have been obvious to employ the leukotriene inhibitors, antihistamines and corticosteroids of Lipworth et al. to reduce C-reactive protein in the body of the user motivated by the teaching of Lipworth that there is an association between allergic inflammation in the upper and lower airway and the teaching of Ridker et al. that C-reactive protein is a marker for underlying systemic

inflammation. As such, as the inflammation is reduced, the C-reactive protein level would be reduced.

Regarding the fexofenadine of instant claim 5 and antihistamine dosages recited in claims 1 and 3, Faham et al. teach fexofenadine is an antihistamine (column 1, lines 28-30) and is administered in doses of from about 10 mg to about 500 mg/day (column 8, lines 36-47). This amount overlaps and encompasses the claimed amount of about 150 to about 250 mg. A *prima facie* case of obviousness exists where the claimed ranges are close enough that one skilled in the art would have expected them to have the same properties.

Regarding the amount of corticosteroid in instant claims 1 and 3, Lipworth disclose 200 and 400 µg/day. The specific safe and effective amount will be vary, with such factors as the particular condition being treated, the physical condition of the patient, the duration of treatment , the nature of the concurrent therapy (if any), the specific dosage form to be used, the carrier employed, the solubility of the formula therein and the dosage regimen desired for the composition. As such, it would have been made obvious to one of ordinary skill in art at the time it was made to employ the recited amounts of corticosteroid motivated by the teaching of Lipworth et al. that dosages of corticosteroids can be lower when combined with a leukotriene inhibitor and an antihistamine for allergic inflammation.

Regarding claim 6, the nasal antihistamine, azelastine is disclosed in Lipworth et al. for the treatment of rhinitis.

Regarding claims 1 and 7, Ridker et al. teach the corticosteroid, fluticasone, as an anti-inflammatory agent useful for reducing C-reactive protein (column 7, line 30).

Regarding the administration of the leukotriene and antihistamine orally and the steroid nasally infused, Lipworth et al. teach that treatment of allergic airway inflammation in the nose with topical corticosteroids may be associated with a commensurate improvement in bronchial hyper responsiveness and asthma control (page 878, column 1). Oral leukotriene inhibitors and loratadine are also disclosed (page 878, column 2).

Thus the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Accordingly, for the above reasons, the claims are deemed properly rejected and none are allowed.

Response to Arguments

Applicant states that claims 1 and 3-9 are amended, claims 2 and 14 are cancelled and claims 1-13 and 15-20 are withdrawn. Applicant is reminded that claim amendments filed on or after July 30, 2003 must comply with 37 CFR 1.121(c) which states:

(c) Claims Amendments to a claim must be made by rewriting the entire claim with all changes (e.g., additions and deletions) as indicated in this subsection, except when the claim is being canceled. Each amendment document that includes a change to an

existing claim, cancellation of an existing claim or addition of a new claim, must include a **complete listing of all claims ever presented**, **including the text of all pending and withdrawn claims, in the application**. The claim listing, including the text of the claims, in the amendment document will serve to replace all prior versions of the claims, in the application. In the claim listing, the status of every claim must be indicated after its claim number by using one of the following identifiers in a parenthetical expression: (Original), (Currently amended), (Canceled), (Withdrawn), (Previously presented), (New), and (Not entered)

(1) Claim listing. All of the claims presented in a claim listing shall be presented in ascending numerical order. Consecutive claims having the same status of "canceled " or "not entered " may be aggregated into one statement (e.g., Claims 1 –5 (canceled)). The claim listing shall commence on a separate sheet of the amendment document and the sheet(s) that contain the text of any part of the

claims shall not contain any other part of the amendment.

(2) When claim text with markings is required. All claims being currently amended in an amendment paper shall be presented in the claim listing, indicate a status of "currently amended, " and be submitted with markings to indicate the changes that have been made relative to the immediate prior version of the claims. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed

within double brackets if strike-through cannot be easily perceived. Only claims having the status of "currently amended," or "withdrawn" if also being amended, shall include markings. If a withdrawn claim is currently amended, its status in the claim listing may be identified as "withdrawn — currently amended."

(3) When claim text in clean version is required. The text of all pending claims not being currently amended shall be presented in the claim listing in clean version, i.e., without any markings in the presentation of text. The presentation of a clean version of any claim having the status of "original," "withdrawn" or "previously presented" will constitute an assertion that it has not been

changed relative to the immediate prior version, except to omit markings that may have been present in the immediate prior version of the claims of the status of "withdrawn" or "previously presented." Any claim added by amendment must be indicated with the status of "new" and presented in clean version, i.e., without any underlining.

(4) When claim text shall not be presented; canceling a claim.

(i) No claim text shall be presented for any claim in the claim listing with the status of "canceled" or "not entered."

(ii) Cancellation of a claim shall be effected by an instruction to cancel a particular claim number. Identifying the status of a claim in the claim listing as "canceled" will constitute an instruction to cancel the claim.

(5) Reinstatement of previously canceled claim. A claim which was previously canceled may be reinstated only by adding the claim as a "new" claim with a new claim number.

Regarding claims 1 and 3-9, rejected under 35 U.S.C. 103(a) as being unpatentable over Lipworth et al. (U), Ridker et al. U.S. Patent No. 6,040,147 A and Faham et al. U.S. Patent No. 6,723,348 B2, applicant asserts that it does not teach the combination of a corticosteroid with a leukotriene inhibitor, and an antihistamine for reducing the levels of highly sensitive C-reactive protein in the body of a user and Ridker and Faham do not teach or suggest the combination of a corticosteroid with a leukotriene inhibitor and an antihistamine for such. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Lipworth teach effective doses of leukotriene inhibitor (montelukast 10 mg/day) and (antihistamine) cetirizine (10 mg/day) as well as (corticosteroids) budesonide and mometasone 400µg daily and 200 µg daily (page 879, column 1). It lacks a teaching of reducing C-reactive protein levels. Ridker et al. teach that C-reactive protein is a marker for underlying systemic inflammation (column 1, lines 60-61). It would have been obvious to employ the leukotriene inhibitors, antihistamines and corticosteroids of Lipworth et al. to reduce C-reactive protein in the body of the user motivated by the teaching of Lipworth that there is an association between allergic inflammation in the upper and lower airway and the teaching of Ridker et al. that C-reactive protein is a marker for underlying systemic inflammation. As such, as the inflammation is reduced, the C-reactive protein level would be reduced.

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Donna Jagoe /D. J./
Examiner
Art Unit 1614

July 13, 2009

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614